

For people with certain neurologic conditions or brain injuries



***Uncontrollable
crying?***



***Uncontrollable
laughing?***

***It could be a sign of
PseudoBulbar Affect (PBA)***



NUEDEXTA[®]

(dextromethorphan HBr and
quinidine sulfate) Capsules

20mg/10mg

There are risks associated with using NUEDEXTA. Please see Important Safety Information inside and accompanying full Prescribing Information.

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NUEDEXTA is not approved to treat emotional symptoms other than involuntary crying and/or laughing that may occur with certain neurologic conditions.

Please see Important Safety Information on pages 14-15 and accompanying full Prescribing Information.



Welcome!

You're about to learn about **PBA** and NUEDEXTA (dextromethorphan hydrobromide and quinidine sulfate) 20 mg/10mg capsules.

NUEDEXTA is the first and only prescription medication specifically approved by the FDA to treat **PseudoBulbar Affect (PBA)**.

Pronunciation: SOO-doh-BUHL-bahr AF-ekt



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20_{mg}/10_{mg}

What is PBA?

Pseudo**B**ulbar **A**ffect (**PBA**) is a neurologic condition that can occur when certain neurologic diseases or brain injuries damage the areas of the brain that control normal expression of emotion. This damage can disrupt brain signaling, causing a 'short circuit' and triggering episodes of crying or laughing that are often sudden and exaggerated or do not match what the person is feeling inside.

Who gets PBA?

Though you may have never heard of PBA prior to your diagnosis, you're not alone. Nearly two million Americans with certain neurologic conditions or brain injuries are estimated to suffer from it. PBA doesn't discriminate. It can affect men and women, old and young.

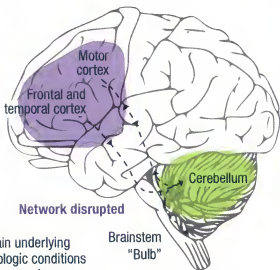
Conditions or injuries that can lead to PBA include:

- Alzheimer's disease or other dementias
- Stroke
- Traumatic brain injury (TBI)
- Multiple sclerosis (MS)
- Parkinson's disease
- Lou Gehrig's disease (ALS)

To learn more, visit NUEDEXTA.com

The Science of PBA

PBA was first described in medical literature more than 130 years ago by Charles Darwin. Over the years, doctors have called PBA by different names such as “emotional incontinence” or “pathological laughing and crying.” Though the names may change, the symptoms are the same.



Network disrupted

Certain underlying neurologic conditions may cause damage that disrupts the normal control of emotional expression.

Brainstem
"Bulb"

**Involuntary
laughing/crying**



One of the jobs of the brain is to figure out how we feel in the moment. That information is then sent down to the brainstem, also known as the “bulb.” The brainstem then sends signals to the face and other parts of the body that show emotion. PBA is believed to be the result of a disruption of these signals.

*"Once my daughter
fell and hurt herself,
and I couldn't
stop laughing."*

*—Bernadetta B.,
PBA patient
taking NUEDEXTA*



An Emotional Disconnect

Patients with PBA describe uncontrollable outbursts of crying or laughing that aren't connected to the way they're feeling inside. One telltale sign of a PBA episode is that the outburst is *inappropriate* for the situation. Many patients tell stories of laughing at funerals or crying when they heard something that actually made them happy.

In other situations, the emotions may be appropriate, but they're *exaggerated* – they're more intense or last longer than is called for. It's common for people to cry when they see a touching movie or TV commercial, but a person with PBA may sob deeply and excessively for a long time.

PBA & Depression

PBA is not depression. However, some patients may have both conditions. PBA and depression should be diagnosed separately for appropriate treatment. Talk with your doctor.

Clinical Characteristics	PBA	Depression
Emotional expression	Crying, laughing, or both	Crying
Underlying neurologic condition	Neurologic disease or brain injury always present	May or may not have underlying neurologic disorder
Episode length of time	Seconds to minutes; brief	Weeks to months; on-going mood
Ability to control episodes	Uncontrollable	May be moderated or controlled
Emotional experience	Exaggerated or does not match feelings inside	Emotions match mood of sadness inside
Accompanying thoughts	Outbursts have no specific link to underlying thoughts	Worthlessness, hopelessness, thoughts of death

Uncontrollable crying?



Uncontrollable laughing?

Help control PBA with NUEDEXTA

NUEDEXTA is the first and only prescription medication specifically approved to treat the symptoms of PBA, uncontrollable crying and/or laughing. It is not an antidepressant and is not approved to treat depression or other emotional symptoms that may occur with certain neurologic conditions.


NUEDEXTA is made up of dextromethorphan and quinidine, two known medicines that have been used separately to treat conditions other than PBA.

NUEDEXTA is thought to act on areas of the brain responsible for emotional responses. With NUEDEXTA, episodes of unwanted crying or laughing can be reduced or eliminated altogether for some patients.

Important Safety Information

NUEDEXTA and certain other medicines can interact, causing serious side effects. If you take certain drugs or have certain heart problems, NUEDEXTA may not be right for you. Tell your doctor if you or a family member has ever had any heart disease or problems. These are not all the possible risks of NUEDEXTA.

To learn more, visit NUEDEXTA.com



*"With NUEDEXTA,
the crying episodes
have gone way
down."*

*—Charles D., PBA
patient taking
NUEDEXTA*

Individual results may vary

NUEDEXTA is clinically proven

In clinical trials, many patients experienced fewer PBA episodes after the first week of taking NUEDEXTA. What's more, many patients were completely free of PBA episodes by the end of the study. Your results may vary.

Tell your doctor if your PBA episodes continue or get worse. You should periodically reassess the need for treatment as PBA symptoms may sometimes improve on their own.



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quinidine sulfate) Capsules

20mg/10mg

Taking NUEDEXTA

Only your doctor can decide if NUEDEXTA is right for you. Take NUEDEXTA exactly as your doctor prescribes it.

Day 1-7



For the first week, take 1 capsule each morning.

Day 8



12 hours



Beginning on day 8, increase your dose to 2 capsules per day – 1 capsule every 12 hours.

NUEDEXTA may be taken with or without food.

If you forget to take 1 or more capsules, do not take a double dose. Take your next dose of NUEDEXTA in the prescribed amount at the usual time. Do not take more than 2 capsules in a 24-hour period. Make sure that 12 hours pass between doses.

Continuing on NUEDEXTA

It is important to continue your treatment as prescribed by your doctor. Your doctor may want to periodically evaluate whether you need to continue your treatment. In some cases, PBA symptoms may improve on their own over time.

To learn more, visit NUEDEXTA.com

Please see Important Safety Information on pages 14-15 and accompanying full Prescribing Information.



"I wanted more control over my PBA outbursts... and with NUEDEXTA I got it."

—David D., PBA patient taking NUEDEXTA

Individual results may vary

Important Safety Information

The most common side effects of NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, swelling of feet and ankles, urinary tract infection, feeling like you have the flu, elevated liver enzyme, and gas. These side effects were seen in 13% or less of patients taking NUEDEXTA. These are not all the possible risks of NUEDEXTA. Tell your doctor about any side effect that bothers you or does not go away.



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NUEDEXTA patient support and savings

Avanir Pharmaceuticals, the maker of NUEDEXTA, is committed to supporting patients with PBA.



– Co-pay savings card

If you have private insurance, the NUEDEXTA co-pay savings card will allow you to pay no more than \$30 for your next NUEDEXTA prescriptions and refills. To get your co-pay savings card, visit www.NUEDEXTAsavings.com. Certain restrictions may apply.

– Out-of-pocket Assistance Program – Medicare Part D

Avanir supports Patient Services, Inc. (PSI), a national nonprofit organization that provides financial assistance to patients with chronic illnesses. If you have Medicare Part D insurance and cannot afford your out-of-pocket costs for medication, PSI may be able to help.

***To learn more, visit NUEDEXTA.com
or call 1-855-4NUEDEX [468-3339]***

– ***NUEDEXTA Patient Assistance Program***

If you are prescribed NUEDEXTA and have limited income and little to no insurance or prescription drug coverage, you may be eligible to receive NUEDEXTA for free.

– ***Reimbursement support***

The Nuedexta patient support team can help with your insurance reimbursement questions and assisting with any required paperwork.

Useful tools

Go to www.NUEDEXTA.com to get access to these useful tools:

– ***Episode Tracker.*** This convenient weekly chart is a great way to monitor the effects of NUEDEXTA on your PBA episodes.

– ***Medicines Chart.*** Use this form to list all the medications you're currently taking, Share this list with your doctor during each visit.

– ***Hear from others who know exactly what you're going through.*** The NUEDEXTA website features personal stories and videos of PBA patients and their caregivers who share firsthand experiences with PBA and how NUEDEXTA has helped them.



Scan this tag to go to NUEDEXTA.com to hear the personal stories of patients with PBA and their loved ones.



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quinidine sulfate) Capsules

20mg/10mg

Important Safety Information for patients

NUEDEXTA® (dextromethorphan hydrobromide and quinidine sulfate) 20mg/10mg capsules are approved for the treatment of pseudobulbar affect (PBA). PBA is a medical condition that causes sudden, frequent and involuntary bouts of crying and/or laughing in people living with certain neurologic conditions or brain injuries. Studies to support the approval of NUEDEXTA were done in patients with multiple sclerosis (MS) or amyotrophic lateral sclerosis (ALS). An additional safety study included a variety of other neurologic populations. NUEDEXTA is not approved to treat emotional symptoms other than involuntary crying and/or laughing that may occur with certain neurologic conditions.

NUEDEXTA and certain other medicines can interact causing serious side effects. People taking MAOIs (within the preceding or following 14 days), quinidine, or quinidine related drugs, and certain other medications should not take NUEDEXTA. Tell your doctor about all medicines, herbal supplements, and vitamins you are taking before you start or while you are taking NUEDEXTA.

Some people can have an allergic reaction to NUEDEXTA. Call your doctor right away if you experience lightheadedness, chills, fever, nausea, or vomiting while taking NUEDEXTA.

NUEDEXTA may cause serious side effects, including changes in heart rhythm (QTc prolongation). Tell your

To learn more, visit NUEDEXTA.com

doctor if you or a family member has or ever had any heart disease or problems. If you have certain heart problems, NUEDEXTA may not be right for you. Your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA. If you feel faint or lose consciousness, call your doctor right away.

NUEDEXTA may make you dizzy. Be extra careful not to fall, especially if you have a hard time walking or a problem with falling.

The most common side effects of NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, swelling of feet and ankles, urinary tract infection, feeling like you have the flu, abnormal liver tests, and gas. These side effects were seen in 13% or less of patients taking NUEDEXTA. Those are not all the possible risks of NUEDEXTA. Tell your doctor about any side effect that bothers you or does not go away.

For more information please refer to the accompanying full Prescribing Information or visit NUEDEXTA.com. This important safety information is not meant to replace discussions with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 800-FDA-1088.



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Are PBA episodes affecting you?

In the last week,

- Have you avoided spending time with family or friends because of unpredictable episodes of crying or laughing?
- Have you found yourself crying in an inappropriate situation and been unable to control it?
- Have friends or family told you that you seem to laugh at things that really aren't funny?
- Have there been situations where you felt fine one minute then were crying the next for no apparent reason?
- Have you found yourself being easily overcome by crying or laughing?

If you answered "yes" to any of these questions, take the short assessment for PBA here and share the results with your doctor.



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Please see accompanying
full Prescribing Information.

Do I have PBA?

The PBA assessment was developed by healthcare professionals and is called the Center for Neurologic Study Liability Scale (CNS-LS). Simply answer the 7 questions and add up your score. If it's 13 or higher, that may suggest you are having PBA symptoms. This assessment tool is not intended to substitute for professional medical assessment and/or advice. Please consult with your doctor.

Take the assessment

Fill out this PBA assessment and take it to your doctor.

Name: _____

Date of assessment: _____

Underlying Neurological Condition:

- ☐ Alzheimer's Disease or Dementia
- ☐ Stroke
- ☐ Traumatic Brain Injury (TBI)
- ☐ Multiple Sclerosis (MS)
- ☐ Parkinson's Disease
- ☐ Lou Gehrig's Disease (ALS)
- ☐ Other Neurologic Condition

The Center for Neurologic Study-Lability Scale (CNS-LS).

Using the scale below, please write the number that describes the degree to which each item applies to you DURING THE PAST WEEK. Write only 1 number for each item.

Applies never	Applies rarely	Applies occasionally	Applies frequently	Applies most of the time
1	2	3	4	5

Assessment Questions		Answers
1	There are times when I feel fine one minute, and then I'll become tearful the next over something small or for no reason at all.	
2	Others have told me that I seem to become amused very easily or that I seem to become amused about things that really aren't funny.	
3	I find myself crying very easily.	
4	I find that even when I try to control my laughter, I am often unable to do so.	
5	There are times when I won't be thinking of anything happy or funny at all, but then I'll suddenly be overcome by funny or happy thoughts.	
6	I find that even when I try to control my crying, I am often unable to do so.	
7	I find that I am easily overcome by laughter.	

TOTAL SCORE _____

Frequently asked questions about NUEDEXTA

How does NUEDEXTA treat PBA?

- Although the exact way in which NUEDEXTA works in people is unknown, it is thought to act on areas of the brain responsible for emotional responses and is specifically targeted to treat PBA.

How long does it take NUEDEXTA to start working?

- In a clinical trial, many patients experienced fewer PBA episodes after the first week of taking NUEDEXTA. Your individual results may vary.

Do I continue to take my other medicines?

- Your doctor may prescribe NUEDEXTA in addition to or in place of other medications you may be taking.
- NUEDEXTA and certain other medicines can interact causing serious side effects. Be sure to tell your doctor about all medicines, supplements and vitamins that you take before starting NUEDEXTA. Before starting a new medicine, remind your doctor if you are taking NUEDEXTA.

What are the most common side effects?

- The most common side effects of NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, swelling of feet and ankles, urinary tract infection, feeling like you have the flu, elevated liver enzymes and gas. The side effects were seen in 13% or less of patients taking NUEDEXTA. Side effects of NUEDEXTA tend to be mild to moderate and generally decrease over time. Tell your doctor about any side effect that bothers you or does not go away.

Ask your doctor

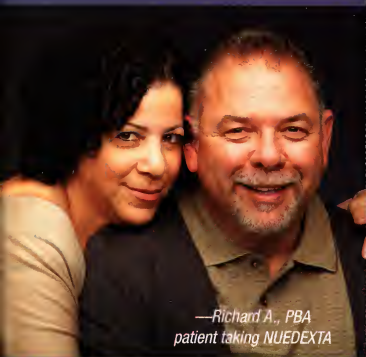
Before considering any medication, you should speak with your doctor to make sure it's right for you. Below you'll find a list of discussion points to bring to your next appointment.

- Do you think I have PBA?*
- How is PBA different from depression?*
- Can NUEDEXTA help me control my PBA outbursts?*
- What can I expect from taking NUEDEXTA?*
- Can I safely continue to take my other medications along with NUEDEXTA?*

Important Safety Information

NUEDEXTA 20 mg/10 mg capsules are approved for the treatment of PBA. PBA is a medical condition that causes sudden, frequent and involuntary bouts of crying and/or laughing in people living with certain neurologic conditions or brain injury. NUEDEXTA is not approved to treat emotional symptoms other than involuntary crying and/or laughing that may occur with certain neurologic conditions.

NUEDEXTA and certain other medicines can interact, causing serious side effects. If you take certain drugs or have certain heart problems, NUEDEXTA may not be right for you. These are not all the possible risks of NUEDEXTA.



—Richard A., PBA
patient taking NUEDEXTA

Richard's PBA Story

Back in 2004 when I was on vacation with Rose and the kids, I was hit by a drunk driver. As a result, I suffered a traumatic brain injury. Since then, I've struggled with a lot of physical and neurologic issues. But the crying outbursts were really hard on all of us. It's embarrassing for a grown man to just suddenly burst into tears, especially in social situations. I was lucky that my doctor knew this was pseudobulbar affect (PBA) and prescribed NUEDEXTA because it has really helped minimize the outbursts.

Individual results may vary.




Scan this tag to hear
Richard and Rose share
their experience with PBA
and NUEDEXTA.



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*"I feel better
knowing there are
other people going
through this and that
we can actually get
some help."*

*—Shevoney D., PBA
patient taking
NUEDEXTA*

Individual results may vary



Scan this tag to go to NUEDEXTA.com to hear
the personal stories of Shevoney and other
patients with PBA and their loved ones.

Questions?
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